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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/555,964	09/08/00	SHINITZKY	M 24259

HM12/0504

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WASHINGTON DC 20005

EXAMINER
HUYNH, P

ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 05/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/555,964

Applicant(s)

SHINITZKY ET AL.

Examiner

"Neon" Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. **Please note** the location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Phuong N. Huynh, Art Unit 1644, Group 1644, Technology Center 1600.
2. Applicant's Status Inquiry, filed 4/20/01 (Paper No. 8) is acknowledged.
This Office Action should serve in response to said inquiry.
3. The Preliminary Amendment, filed 09/08/00 (Paper No. 5) is acknowledged.
Claims 1-5 have been canceled.
Claims 11-13 have been added.
Claims 6-13 are pending and being acted upon in this Office Action.
4. The drawings, filed 09/08/00, is not approved.
5. It is noted that the reference (AC) as cited in PTO-1449 **missing the date and the pertinent pages**. In order to have the reference printed on such resulting patent, a separate listing, preferably on a PTO-1449 form including the Authors, Title, date, publisher, Edition or volume and pertinent pages must be listed on a PTO-1449 and a copy of those references must provide to the office.
6. Applicant should amend the first line of the specification to indicate the status of the priority documents, i.e., This application is a 371 of PCT/IL98/00592, filed 12/07/1998 and claims benefit of Foreign Application Israel 122490, filed 12/07/1997. See MPEP 1302.04.
7. The declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.
The declaration is defective because:
The words are **not** legible.

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8. Appropriate correction in the specification is required. The page numbering is duplicate (See page 3).
9. The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.
 - (a) Title of the Invention.
 - (b) cross-references to Related Applications (if any).
 - (c) Statement as to rights to inventions made under Federally sponsored research and development (if any).
 - (d) Background of the invention.
 1. Field of the Invention.
 2. Description of the Related Art including information disclosed under 37 C.F.R. §§ 1.97-1.99.
 - (e) Summary of the Invention.
 - (f) Brief Description of the Drawing.
 - (g) Description of the Preferred Embodiment(s).
 - (h) Claim(s).
 - (i) Abstract of the Disclosure.
10. The specification is objected to because of the following: (1) the page numbering is not consecutively numbered due to a duplicate page 3; (2) the references are not listed on a PTO-1449 and (3) a copy of those references have not been provide to the office.
11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
12. Claims 7, 8, 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "an active component" as recited in claims 7 and dependent claims 11 has no antecedent basis in the claim.

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The phrase “a positive result being a reaction above that which is observed in non-schizophrenic subjects” as recited in claims 7-9 and 11-13 is indefinite and ambiguous as the metes and bounds of the claimed invention. As written in the claims, one of ordinary skill in the art can not appraise the metes and bounds of the claimed invention. This rejection could be overcome by reciting the condition on pages 10 and 13, including the diameter of the wheel at the site of injection.

The phrase “and/or” as recited in claims 8 and dependent claim 11 is not appropriate in the claims. It is suggested that applicants amend the claims to recite either “and” or “or”.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinitzky *et al.* (WO 97/13152, PTO 1449) and Kessler *et al* (Demenita 6(6): 330-3; 1995; PTO 892) and in view of Burbacae *et al* (ZH Nevropatol Psikhiatr IM S S Korsakova 86(1): 103-105; 1986).

Shinitzky *et al.* (PTO 1449) teach a method of preparing a reagent for use in diagnosing dermantia by collecting blood from a number of individuals, isolating platelet from the blood samples (See entire document, page 8 in particular) and preparing platelet proteins by isoelectric

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focussing (See page 10) wherein said proteins have a pI within the range of above about 6.5 to about 9.5 (See page 12, Fig 4).

Shinitzky *et al.* (PTO 1449) differs from the claimed invention preparing platelet protein from individuals with Alzheimer-type dementia.

Kessler *et al* (PTO 892) teach that platelet proteins from young 21-year old schizophrenic patients have an increase in the number of dense granule per platelet with characteristics similar to platelets of 37-year old healthy individuals (See entire document, page 332, Fig 2, Table 2, and right column). Furthermore, the platelet cell size in schizophrenic patients increases compared with age match healthy controls (See abstract in particular).

Burbaea *et al.* teach the use of delayed type hypersensitivity reaction (DTH) to neuroproteins in schizophrenic patients (See abstract in particular).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use delayed type hypersensitivity reaction as taught by Burbaea to diagnose schizophrenia using the platelet proteins as taught by Shinitzky and Kessler. One having ordinary skill in the art would have been motivated to use proteins from platelet to screen the population with psychiatric disorders such as schizophrenia because platelets of schizophrenics are definitively different than normal individual as taught by Kessler.

16. No claim is allowed.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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18. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

May 2, 2001



Patrick J. Nolan, Ph.D.

Primary Examiner

Technology Center 1600